

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Meeting of the Oncologic Drugs Advisory Committee (ODAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
November 6, 2014

DRAFT AGENDA

During the morning session, the committee will discuss new drug application (NDA) 205353, panobinostat capsules, application submitted by Novartis Pharmaceuticals Corporation. The proposed indication (use) for this product is in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.

8:00 a.m.	Call to Order and Introduction of Committee	Deborah Armstrong, MD Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	Caleb Briggs, PharmD Designated Federal Officer, ODAC
8:10 a.m.	Opening Remarks	Ann T. Farrell, MD Director Division of Hematology Products (DHP) Office of Hematology & Oncology Products (OHOP), OND, CDER, FDA
8:15 a.m.	APPLICANT PRESENTATIONS	
	Introduction	Renaud Capdeville, MD Vice President, Global Program Head Oncology Global Development Novartis Pharmaceuticals Corporation
	Multiple Myeloma	Keith Stewart, MB, ChB Dean for Research, Mayo Clinic in Arizona Vasek and Anna Maria Polak Professorship in Cancer Research
	Clinical Efficacy and Safety	Renaud Capdeville, MD
	Clinical Perspective	Paul G. Richardson, MD R.J. Corman Professor of Medicine Harvard Medical School Dana-Farber Cancer Institute

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DRAFT AGENDA (cont.)

9:00 a.m. **FDA PRESENTATION**

NDA 205353 - Panobinostat (Farydak)

Barry W. Miller, MSN, CRNP
Senior Clinical Analyst
DHP, OHOP, OND, CDER, FDA

Nicole Gormley, MD
Clinical Reviewer
DHP, OHOP, OND, CDER, FDA

9:45 a.m. Clarifying Questions to the Presenters

10:15 a.m. **BREAK**

10:30 a.m. Open Public Hearing

11:00 a.m. Questions to the Committee/Committee Discussion

12:00 p.m. **LUNCH**

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DRAFT AGENDA (cont.)

During the afternoon session, the committee will discuss NDA 206317, ferric pyrophosphate solution, for administration via hemodialysis dialysate, application submitted by Rockwell Medical, Inc. The proposed indications (uses) for this product are for the treatment of iron loss or iron deficiency to maintain hemoglobin in adult patients with hemodialysis-dependent stage 5 chronic kidney disease and to reduce the prescribed dose of erythropoiesis stimulating agent required to maintain desired hemoglobin levels.

1:00 p.m.	Call to Order and Introduction of Committee	Deborah Armstrong, MD Chairperson, ODAC
1:05 p.m.	Conflict of Interest Statement	Caleb Briggs, PharmD Designated Federal Officer, ODAC
1:10 p.m.	Opening Remarks	Ann T. Farrell, MD Director Division of Hematology Products (DHP) Office of Hematology & Oncology Products (OHOP), OND, CDER, FDA
1:15 p.m.	APPLICANT PRESENTATIONS	
	Triferic Introduction	Ajay Gupta, MBBS, MD Chief Scientific Officer Rockwell Medical, Inc.
	Clinical Landscape	Steven Fishbane, MD Chief, Division of Kidney Disease and Hypertension North Shore University Hospital and Long Island Jewish Medical Center Professor of Medicine Hofstra North Shore-LIJ School of Medicine
	Triferic Mechanism of Action	Gary Brittenham, MD James A. Wolff Professor of Pediatrics and Professor of Medicine Columbia University Medical College

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Triferic Efficacy

Raymond Pratt, MD, FACP

Chief Medical Officer

Rockwell Medical, Inc.

Triferic Safety

Vivian Lin, MD

Senior Director Clinical Research

Rockwell Medical, Inc.

Clinical Perspective

Steven Fishbane, MD

2:00 p.m.

FDA PRESENTATION

NDA 206317 - Triferic

Min Lu, MD, MPH

Clinical Reviewer

DHP, OHOP, OND, CDER, FDA

Lola Luo, PhD

Statistical Reviewer

Division of Biostatistics V (DBV)

Office of Biostatistics (OB)

Office of Translational Science (OTS)

CDER, FDA

2:45 p.m.

Clarifying Questions to the Presenters

3:15 p.m.

BREAK

3:30 p.m.

Open Public Hearing

4:00 p.m.

Questions to the Committee/Committee Discussion

5:00 p.m.

ADJOURNMENT